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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,860	04/16/2002	Peter James Brian Lamb	ADMS-0003	8533
23377	7590	03/21/2006	EXAMINER	
WOODCOCK WASHBURN LLP ONE LIBERTY PLACE, 46TH FLOOR 1650 MARKET STREET PHILADELPHIA, PA 19103			GIBSON, KESHIA L	
			ART UNIT	PAPER NUMBER
			3761	

DATE MAILED: 03/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/031,860	Applicant(s) LAMB, PETER JAMES BRIAN	
	Examiner Keshia Gibson	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/6/06 has been entered.

Response to Arguments

2. Applicant's arguments with respect to claims 1-15 have been considered but are moot in view of the new ground(s) of rejection.

Claim Objections

3. Claims 2 and 4 are objected to because of the following informalities: it is suggested that the article "a" be added so that the claims read "a transverse cross section." Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 3, 8, and 13-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Waring (US 2,007,626).

In regard to Claims 1, 3, 8, 14, Waring discloses a device (capsule applicator) comprising an elongate, monolithic body having a gripping portion and an elongate straight barrel, a passage, and a flexible plunger slidingly located in the passage and follows the curvature of the passage; the passage is configured to receive a solid object or medicament, extends through the gripping portion and barrel, has an outlet at a free end of the barrel, and has a curved portion located in the gripping portion (Figs., page 1, lines 1-15 and lines 34-13).

In regard to Claim 13, the device is intended to be gripped by a hand and meets the structural limitations of the claimed invention. As such, the device "can be," or is capable of, being gripped as claimed by the present invention.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 2 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Waring.

In regard to Claims 2 and 4, Waring discloses the claimed invention but does not expressly disclose that the applicator has a roughly triangular cross-section in the transverse direction. However, a change in the shape of a prior art device is a design consideration within the skill of the art. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CPA 1966).

9. Claims 5-6 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Waring.

In regard to Claims 5-6, the passage has an inlet (near 18) remote from its outlet (Fig. 1). Waring discloses that the portion of the passage in the barrel and the portion of the passage near the passage inlet are at an obtuse angle in relation to each other (Fig. 1) but does not expressly disclose specific range of degrees for the angle. However, it would have been obvious to one of ordinary skill in the art to provide the obtuse angle between a specific range of degrees, since it has been held that where the general

conditions of a claim are disclosed in the prior art, discovering the optimum or workable range involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

In regard to Claim 11, Waring discloses the claimed invention but does not expressly disclose a Shore A hardness for the barrel material. However, the rigidity (hardness) of barrel of the applicator affects the ability of the applicator to support a medicament, or other object to be inserted into a body cavity, to be inserted into a body cavity, and to withstand any forces generated by moving the plunger within the applicator. As such, the hardness of the barrel is considered to be a result effective variable. Thus, it would have been obvious to one of ordinary skill in the art to provide the barrel material with a specific Shore A hardness, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

10. Claims 9 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Waring in view of Hanke (US 3,830,236).

In regard to Claims 9 and 15, Waring discloses the claimed invention but does not expressly disclose that the applicator chamber is surrounded by an upper and a lower portion that are displaced toward each other during insertion of the applicator. Hanke disclose an applicator for hygenic material and further teach surrounded the chamber with a plurality of petal-like segments (portions) in order to protect the contents of the applicator from contamination and also to reduce the diameter of the leading end of the applicator in order to facilitate insertion into a body orifice (column 1, lines 14-28). The

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segments are considered to be displaceable toward each other during insertion (column 1, line 1-column 2, line 4). One of ordinary skill in the art would have been motivated to modify the applicator of Waring to provide for petal-like segments, as taught by Hanke, since doing so would protect the contents of the applicator from contamination and also to reduce the diameter of the leading end of the applicator in order to facilitate insertion into a body orifice. Thus, it would have been obvious to one of ordinary skill in the art to modify the applicator of Waring to provide for petal-like segments, as taught by Hanke, since doing so would protect the contents from contamination and also facilitate insertion of the applicator into a body orifice.

11. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Waring in view of Gamache et al. (US 1,224,755).

In regard to Claim 10, Waring discloses a device for depositing a capsule, or similar medicament container, but does not disclose that the barrel further comprises a slit. Gamache et al. discloses an applicator for depositing a solid object into a body cavity and further disclose providing a longitudinally extending slit through the outer surface of the applicator for receiving a string attached to a tampon. One of ordinary skill in the art would have been motivated to modify the applicator of Waring to provide a slit since doing so would allow a tampon string to be easily received by the applicator. Thus, it would have been obvious to one of ordinary skill in the art to modify the applicator of Waring to provide a slit since doing so would allow a tampon string to be easily received by the applicator.

12. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Waring in view of Paul et al. (US 5,158,535).

In regard to Claim 12, Waring discloses the claimed invention except for the body and the plunger being made of paper or paper pulp to make the device disposable. Paul et al. disclose an applicator 10 for insertion of an object into the vagina (abstract, column 3, lines 34-39). The applicator has an elongate body 14, 16 having an elongate barrel 14, a gripping portion 20, a passage (extending from the hollow of enlarged portion 18 through the hollow of the plunger 16), a nonflowable object 12, and a plunger 16. Paul et al. teach that the applicator 10 may be made of cardboard (paper or paper pulp) in order to make it flushable (disposable) (column 7, lines 1-4). One would have been motivated to modify the applicator of Gamache et al. to be made out of paper or paper pulp as taught by Paul et al. since doing so would render the applicator disposable. Thus it would have been obvious to one of ordinary skill in the art to modify the applicator body and plunger of Gamache et al. to be manufactured from paper or paper pulp as taught by Paul et al. since doing so would render the applicator disposable.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Tiemann et al. (US 6190348), Porat (US 6248089), and Anderson et al. (US 6,352,513).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keshia Gibson whose telephone number is (571) 272-7136. The examiner can normally be reached on M-F 8:30 a.m. - 6 p.m., out every other Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Keshia Gibson
Examiner
Art Unit 3761

klg 3/15/06

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

